

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

This Page Blank (uspto)

(12) UK Patent Application (19) GB (11) 2 242 361 (13) A

(43) Date of A publication 02.10.1991

(21) Application No 9105628.3

(22) Date of filing 18.03.1991

(30) Priority data

(31) 9007178

(32) 30.03.1990

(33) GB

(71) Applicant

Smiths Industries Public Limited Company

(Incorporated in the United Kingdom)

765 Finchley Road, London, NW11 8DS,
United Kingdom

(72) Inventor

Martin Thornton Wilson

(74) Agent and/or Address for Service

J M Flint

765 Finchley Road, London, NW11 8DS,
United Kingdom

(51) INT CL⁸

A61M 5/158 5/32

(52) UK CL (Edition K)

A5R RGB

(56) Documents cited

EP 0091227 A1

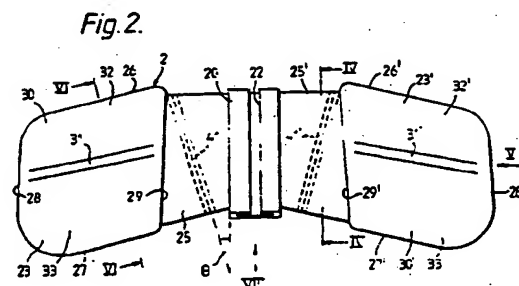
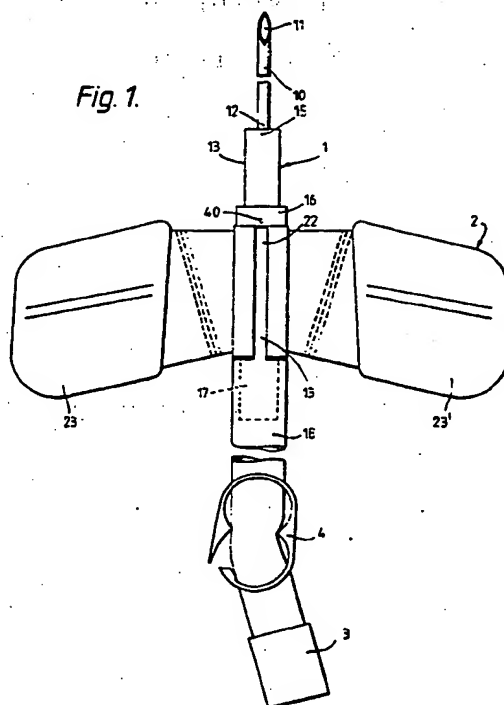
(58) Field of search

UK CL (Edition K) A5R RGB

INT CL⁸ A61M

(54) Intravenous needle assemblies

(57) An intravenous needle assembly has a needle (1) and a handle (2) for use in placing the needle into a vein. The handle has a body portion (20) which surrounds the hub (13) of the needle (1) and is attached via respective hinge portions (25 and 25') to two wings (23 and 23'). The hinge portions (25 and 25') are angled such that when the wings (23 and 23') are folded up they diverge one from the other at the end closer to the tip of the needle (1).



GB 2 242 361 A

Fig. 1.

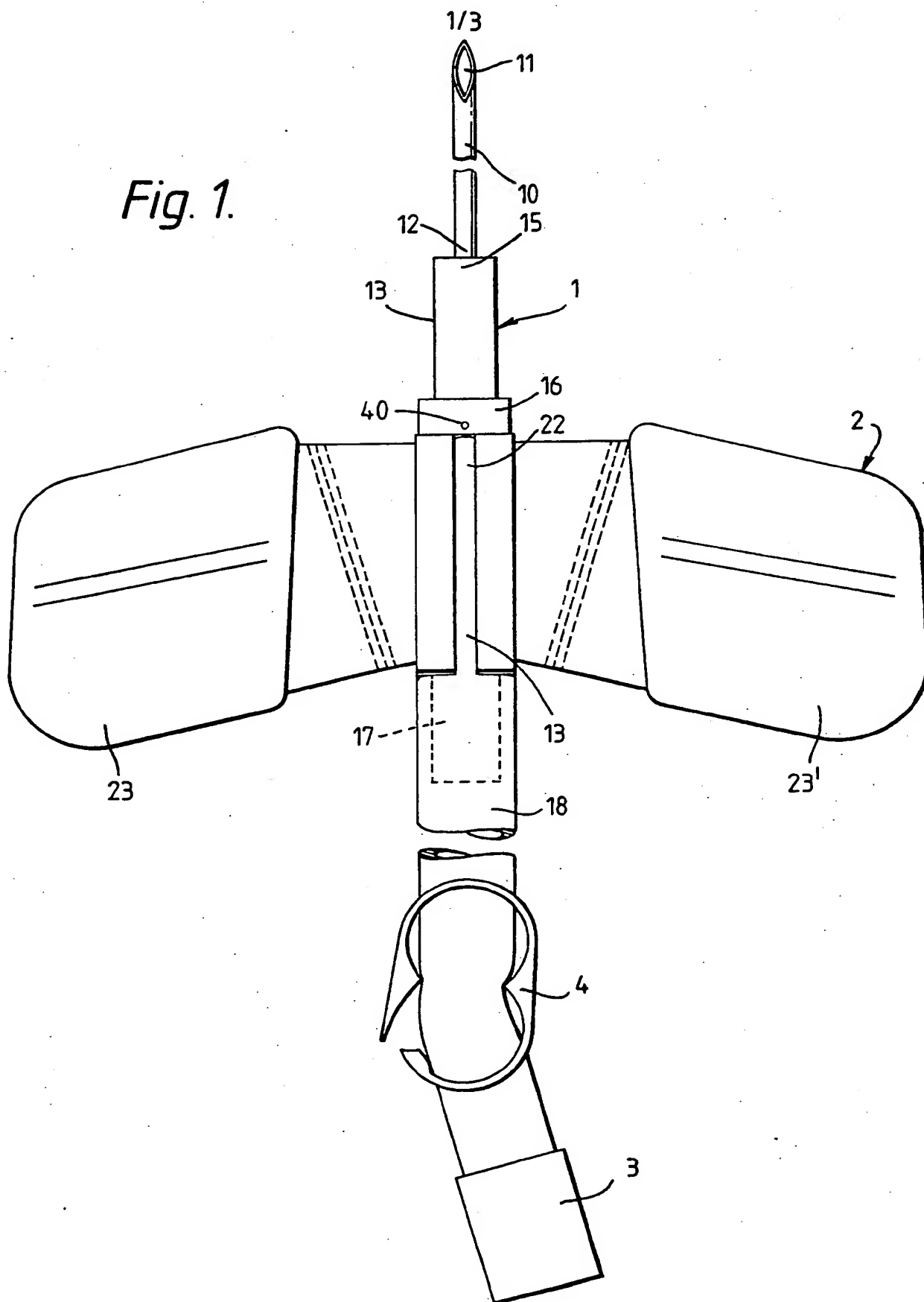


Fig. 2.

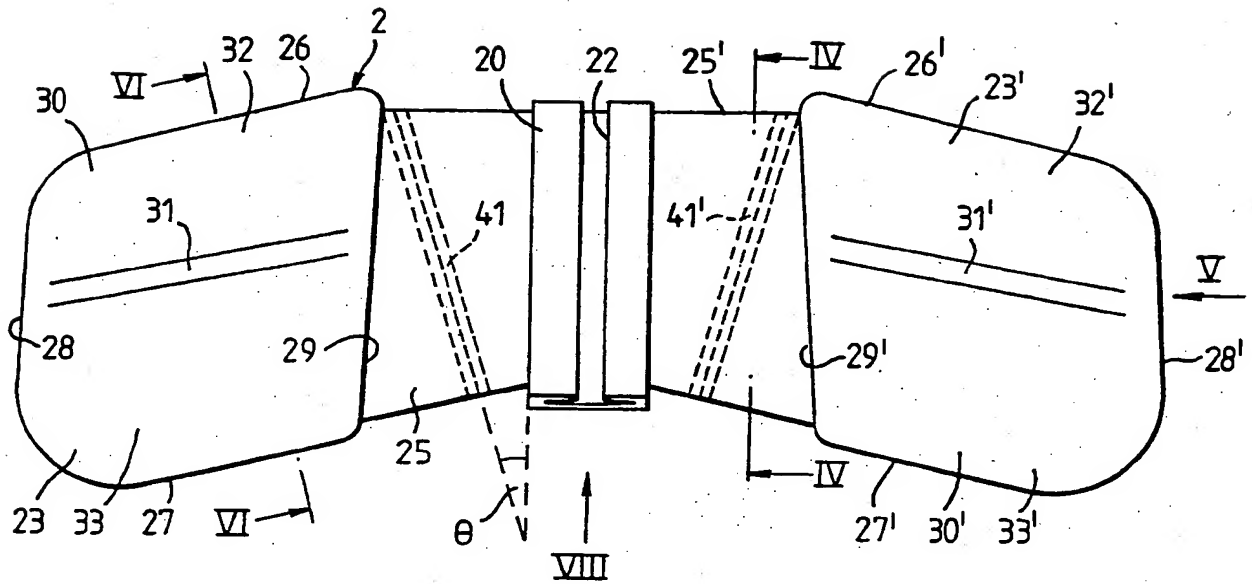
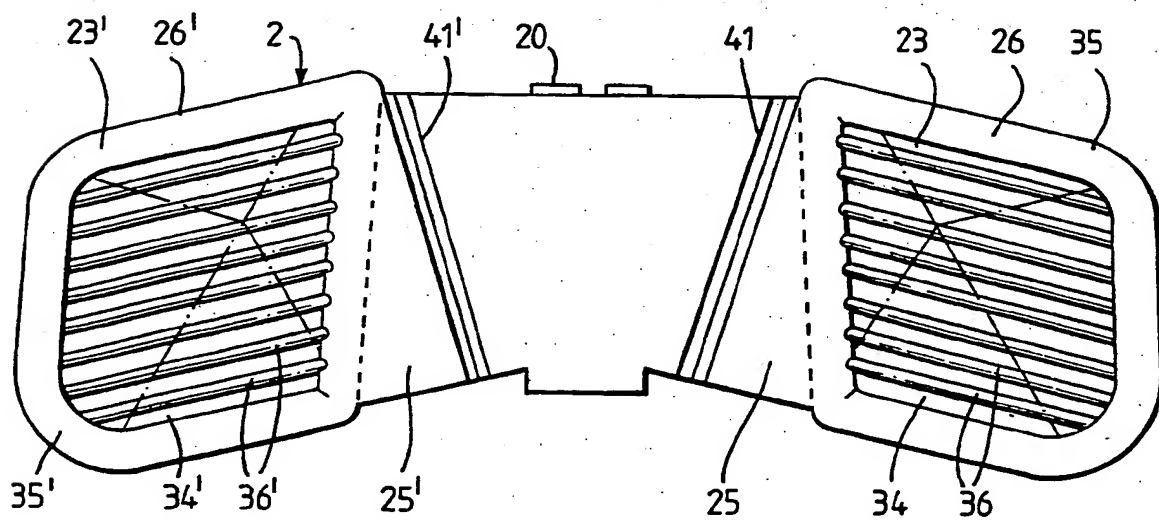


Fig. 3.



3/3

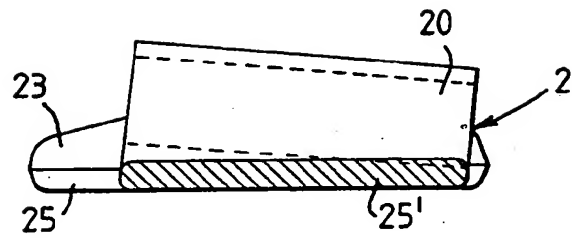


Fig. 4.

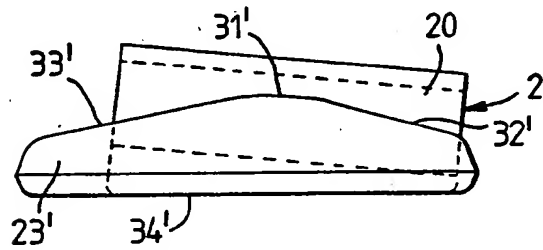


Fig. 5.

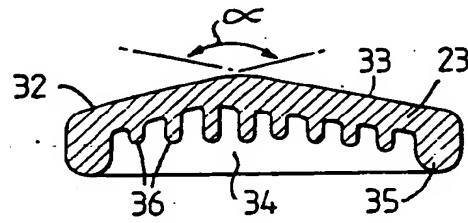


Fig. 6.

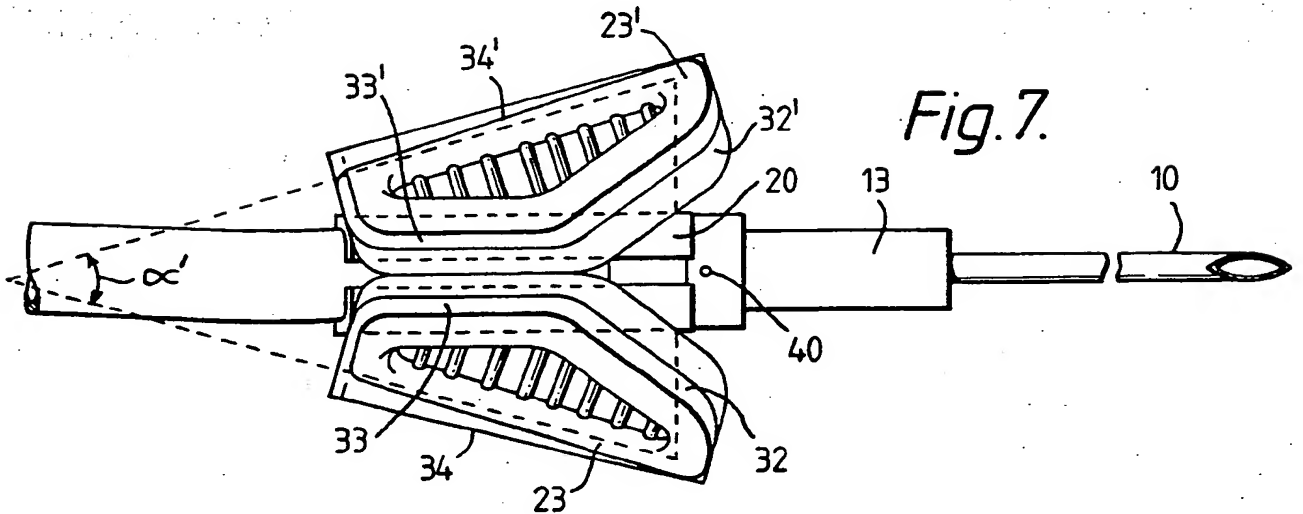


Fig. 7.

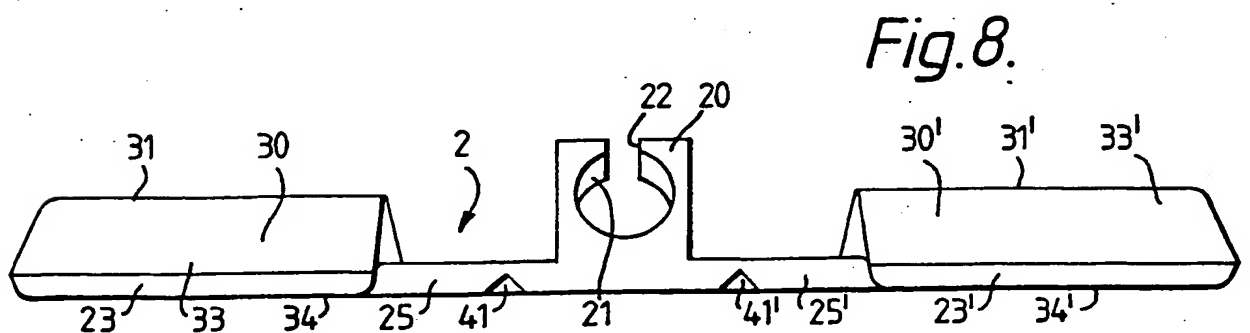


Fig. 8.

INTRAVENOUS NEEDLE ASSEMBLIES

This invention relates to intravenous needle assemblies.

Intravenous needle assemblies of the general type with which the present invention is concerned are known in the art. Examples of such prior art assemblies are described in, for example, United States Patent Nos. 2725058, 3064648, 3640275, 3537451, 3782383, 4015600, 4170993, 4198973, 4300553, British Patents Nos. 1257639, 1274179, 1279852, 1459741, 2088721 European Patent Applications Nos 0033207 0050459, 0091227 and International Application No. WO 81/01518. A variety of devices are commercially available. However the presently available devices show certain deficiencies and disadvantages. Most prior art devices include a handle comprising a pair of oppositely extending wings connected via a hinge or weakened section to a wing hub which holds a pointed hollow needle. To insert the needle into the vein beneath the skin the wings are folded together and grasped by the fingers and thumb. As a result, the forward pressure applied to the needle to put it through the skin is applied above and behind the needle. If the material forming the handle is flexible, the needle may be easily diverted from its path for example, by tough skin. The fingers may slip if the

the handle is wet or contaminated by lubricant.

It is an object of the present invention to provide an improved form of intravenous needle assembly which affords a more positive grip.

According to one aspect of the present invention there is provided an intravenous needle assembly including an intravenous needle member and a handle for use in placing and maintaining the patient end of the needle within a vein, the handle comprising a body portion adapted to receive the needle, the body portion being connected via respective hinge portions to oppositely extending wing portions, the hinge portions being hinged along respective lines angled out of parallel with the needle such that when the wing portions are folded up to be gripped by the user, the lower surface of the wing portions so gripped by the user diverge such that they are further apart at the end closer to the tip of the needle than at the end remote from the needle tip.

Each wing portion is preferably angled on one surface to provide respective faces that lie parallel to another when the wing portions are folded up and gripped by the user. The parallel faces may abut one another when the wing portions are folded up and gripped by the user.

The wing portions preferably have, on said one surface, two angled faces inclined to one another at an angle of approximately 150 degrees.

The body portion is preferably generally square in external section and the upper surface of the body portion may slope down towards its distal end. The upper surface of the body portion preferably slopes down at an angle of approximately 5 degrees to the horizontal.

The body portion preferably has a slot extending along its length connecting with a bore through the body portion. The slot may be arranged to allow the needle member to be inserted into the bore by pushing down into the slot.

The needle member preferably comprises a needle and a hub at the end remote from the needle tip. The needle member may be free to rotate in the body portion. The body portion may be squeezed about the needle member when the wing portions are folded up and gripped by the user.

The lower surface of each of the wing portions is preferably concave and is preferably surrounded by a peripheral wall. The lower surface of each wing portion may be formed with a plurality of ribs. The ribs may extend generally transverse to the axis of the assembly.

The angle between the fold lines and the axis of the assembly is preferably in the range 5 to 45 degrees and may be 15 degrees.

The handle is preferably of plastics material and may be of polypropylene.

An intravenous needle assembly in accordance with the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a plan view of the assembly with the wing portions flat;

Figure 2 is enlarged plan view of a part of the assembly;

Figure 3 is an underside view of a part of the assembly;

Figure 4 is a sectional view of a part of the assembly along the line IV-IV of Figure 2;

Figure 5 is a side elevation view of a part of assembly along the arrow V of Figure 2;

Figure 6 is a cross-sectional view along the line VI-VI of Figure 2;

Figure 7 is a plan view of the assembly with the wings folded up; and

Figure 8 is an end view of a part of the assembly along the arrow VIII of Figure 2.

With reference first to Figure 1, the intravenous needle assembly comprises a needle member 1 and a handle 2 used to grip and manipulate the assembly.

The needle member 1 includes a stainless steel needle 10 having a bevelled, pointed, distal tip 11 and a proximal end 12 which is held fixedly in a moulded plastics hub 13. The hub 13 is of circular section with a central bore which communicates smoothly with the bore of the needle 10. At its distal end 15, the diameter of the hub 13 is such that it forms an interference fit with a needle protector tube (not shown) which protects the needle from contamination and the user from injury prior to use. Adjacent the distal end 15 is an annular flange 16 that provides a stop for the needle protector tube and for the handle 2. The diameter of the proximal end 17 of the hub 13 is such as to fit inside flexible tubing 18 leading from a source of infusion fluid; the tubing 18 is adhered to the hub 13. At its proximal end, the tubing 18 has a female luer connector 3. A pinch clip 4 may be mounted on the tubing 18 for use in preventing flow of infusion liquid.

With reference now to Figures 2 to 8, the handle 2 is injection moulded from a thermoplastic polymer such as a polyolefin. Suitable polyolefins include high-density and low-density polyethylene and polypropylene. A

preferred polyolefin is polypropylene. The polyolefins are hypoallergenic when used in contact with the skin and may be easily colour coded to designate different gauges of needle. The handle 2 includes a body portion 20 which is generally square in external section with its upper surface sloping down at an angle of about 5 degrees to the horizontal towards its distal end. The body portion 20 has a bore 21 of circular section which inclines parallel to the upper surface of the body portion and in which is received the hub 13. The bore 21 opens along the length of the body portion 20 through a slot 22 along its upper surface. The hub 13 of the needle member 1 is free to rotate in the bore 21 but is prevented from moving axially in one direction by the flange 16 and in the other direction by the tubing 18. The incline of the bore 21 directs the tip of the needle 10 downwards into the vein when the handle 2 is flat on the skin. A mark 40 on the flange 16 is used to indicate the attitude of the bevel of the tip of the needle.

The handle 2 also includes two oppositely extending wing portions 23 and 23' linked to the body portion 20 by respective hinge portions 25 and 25'. The wings 23 and 23' are of parallelogram shape with their distal and proximal edges 26 and 27 inclined proximally at an angle of about 75 degrees to the needle axis. The outer and inner edges 28 and 29 of the wings are inclined

at an angle of about 3 degrees to the needle axis. The upper surface 30 of each wing 23 has a pitched roof shape with a ridge 31 of maximum height extending parallel to the distal and proximal edges 26 and 27, midway between them. This divides the upper surface 30 into two angled faces 32 and 33 inclined to one another at an angle α of about 150 degrees. The lower surface 34 of the wing portions 23, as best shown in Figures 3 and 6, is concave, being surrounded by a peripheral wall 35. Within the boundary of the wall 35, the lower surface is formed with eight ribs 36 which extend parallel with the distal and proximal edges 26 and 27 and generally transverse to the axis of the assembly when the wings are folded up. The height of the ribs 36 is such that they do not protrude beyond the wall 35. The shape and thickness of the wings 23 renders them relatively rigid and inflexible.

The hinge portions 25 and 25' are thinner than the wings 23 being about 0.8 mm thick and of trapezium shape with their distal ends being about 5.25 mm wide and their proximal ends being about 5.9 mm wide. Both hinge portions 25 and 25' have a respective fold line 41 and 41' provided by V-shape groove, which extends diagonally across the hinge portion from the outer corner at the distal end of the assembly to the inner corner at the proximal end. The angle θ between the fold lines 41 and 41' and the body portion 20, or axis of the assembly, is

preferably approximately 15 degrees but may be between 5 degrees and 45 degrees.

The fold lines 41 and 41' enable the wing portions 23 and 23' to be folded up to the position shown in Figure 7. When folded up vertically and squeezed together, the proximal faces 33 and 33' on the upper surface 30 and 30' of each wing come into parallel contact with one another. This also causes the proximal faces 33 and 33' to contact opposite edges along the upper surface of the body portion 20. Pressure exerted to bring the proximal faces 33 into contact with one another will squeeze the body portion 20 about the needle hub 13. This closes the slot 22 slightly and prevents the hub 13 rotating relative to the body portion. In the vertical position, the lower faces 34 and 34' of the wing portions 23 and 23' are inclined relative to one another to diverge at an angle α' of approximately 30 degrees. The separation between the lower faces 34 is greater at the distal end, closer the tip 11 of the needle, than at the proximal end.

The polyolefins used to make the handle 2, and polypropylene in particular, have the advantage of being rigid while being capable of forming a hinge portion without becoming brittle on flexing. Such polymers will reversibly accept stress which in the preferred embodiment

allows the needle hub to be held still during insertion with the wings 23 and 23' folded while allowing free rotation of the needle hub 13 when relaxed.

When the wings are gripped by the user in the folded-up position, they come into contact with one another to provide a rigid structure with an angled outer surface provided by the lower surface of the wings. This gives to handle 2 a very secure and positive feel when gripped between the finger and thumb, with a reduced risk of slipping should the surface of the wings become wet. The risk of slipping is further reduced by the concave nature of the lower surface 34 and the ribs 36.

The flexibility of the hinge portions ensures that when the wing portions are released, after insertion in the vein, they can be easily flexed down to their natural, flat state, thereby enabling the assembly to be secured to the patient's skin, in the usual way, by means of adhesive tape laid across the wing portions.

CLAIMS

1. An intravenous needle assembly including an intravenous needle member and a handle for use in placing and maintaining the patient end of the needle within a vein, wherein the handle comprises a body portion adapted to receive the needle, wherein the body portion is connected via respective hinge portions to oppositely extending wing portions, the hinge portions being hinged along respective lines which are angled out of parallel with the needle such that when the wing portions are folded up to be gripped by the user, the lower surface of the wing portions so gripped diverge such that they are further apart at the end closer to the tip of the needle than at the end remote from the needle tip.
2. An intravenous needle assembly according to Claim 1, wherein each of said wing portions is angled on one surface to provide respective faces that lie parallel to one another when the wing portions are folded up and gripped by the user.

3. An intravenous needle assembly according to Claim 2, wherein the said parallel faces abut one another when the wing portions are folded up and gripped by the user.
4. An intravenous needle assembly according to Claim 2 or 3, wherein the wing portions on said one surface have two angled faces inclined to one another at an angle of approximately 150 degrees.
5. An intravenous needle assembly according to any one of the preceding claims, wherein the body portion is generally square in external section.
6. An intravenous needle assembly according to any one of the preceding claims, wherein the upper surface of the body portion slopes down towards its distal end.
7. An intravenous needle assembly according to Claim 6, wherein the upper surface of the body portion slopes down at an angle of approximately 5 degrees to the horizontal.

8. An intravenous needle assembly according to any one of the preceding claims, wherein the body portion has a slot extending along its length connecting with a bore through the body portion.
9. An intravenous needle assembly according to Claim 8, wherein the slot is arranged to allow the needle member to be inserted into the bore by pushing down into the slot.
10. An intravenous needle assembly, wherein the needle member comprises a needle and a hub at the end remote from the needle tip.
11. An intravenous needle assembly according to any one of the preceding claims, wherein the needle member is free to rotate in the body portion.
12. An intravenous needle assembly according to any one of the preceding claims, wherein the body portion is squeezed about the needle member when the wing portions are folded up and gripped by the user.

13. An intravenous needle assembly according to any one of the preceding claims, wherein the lower surface of each of the wing portions is concave and is surrounded by a peripheral wall.
14. An intravenous needle assembly according to any one of the preceding claims, wherein the lower surface of each wing portion is formed with a plurality of ribs.
15. An intravenous needle assembly according to Claim 14, wherein said ribs extend generally transverse the axis of the assembly.
16. An intravenous needle assembly according to any one of the preceding claims, wherein the angle between the fold lines and the axis of the assembly is in the range 5 to 45 degrees.
17. An intravenous needle assembly according to Claim 16, wherein the angle between the fold lines and the axis of the assembly is 15 degrees.

18. An intravenous needle assembly according to any one of the preceding claims, wherein the handle is of plastics material.
19. An intravenous needle assembly according to any one of the preceding claims, wherein the handle is of polypropylene.
20. An intravenous needle assembly substantially as hereinbefore described with reference to the accompanying drawings.
21. Any novel feature or combination of features as hereinbefore described.

This Page Blank (uspto)